

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Eight Weeks of Aerobics Exercise on Depression, Anxiety, and Stress in Women with Subclinical Hypothyroidism

Protocol summary

Study aim

The aim of this study will investigate the effect of eight weeks of aerobic exercise on depression, anxiety, and stress in women with hypothyroidism.

Design

41 patients with hypothyroidism will be selected by simple randomization and will be divided into experimental (n=23) and control groups (n = 18).

Settings and conduct

The present study was a semi-experimental study with pre-test-posttest design with control group. The subjects were randomly divided into two experimental groups (23 patients) and control (n = 18) from among the patients referred to Rasoul-e-Akram Hospital in Abadan city. All subjects participated in this study after informing about the process and the way of doing research and signing written consent. At first, a pre-test was taken from the samples by answering the questions of the DASS-21 questionnaire. The experimental group then participated in an aerobic exercise program for eight weeks, three 60-minute sessions each week. The control group did not participate in any sporting activity properly. After completing the exercise protocol, again, from both groups, the post-test was measured.

Participants/Inclusion and exclusion criteria

Patients with subclinical hypothyroidism can participate in the study, and people with orthopedic problems and heart disease cannot participate in the study.

Intervention groups

Experimental and control groups. The experimental group will participate in an aerobic exercise program for eight weeks, three 60-minute sessions per week. The control group doesn't participate in any sporting activity properly.

Main outcome variables

Depression, anxiety and stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161129031165N3**

Registration date: **2019-08-12, 1398/05/21**

Registration timing: **retrospective**

Last update: **2019-08-12, 1398/05/21**

Update count: **0**

Registration date

2019-08-12, 1398/05/21

Registrant information

Name

Vahid Valiopour Dehnou

Name of organization / entity

Lorestan University

Country

Iran (Islamic Republic of)

Phone

+98 66 3312 0086

Email address

valipour.v@lu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-03, 1397/11/14

Expected recruitment end date

2019-04-04, 1398/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Eight Weeks of Aerobics Exercise on Depression, Anxiety, and Stress in Women with Subclinical Hypothyroidism

Public title

The Effect of Exercise on Depression, Anxiety, and Stress

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age from 30 to 45 years
Consume at least 6 months of Levothyroxine regularly
Female gender

Exclusion criteria:

cardiovascular disease and diabetes alcohol and tobacco use Orthopedic problems

Age

From **30 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **41**

Randomization (investigator's opinion)

Randomized

Randomization description

After referring to the Rasool Akram Hospital in Abdanan city, the subjects will be selected based on their availability and after obtaining consent, and using simple randomization method (Flip the coin) assigned into two groups: experimental group (eight weeks aerobic training) and control group (doing daily activities).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

Street address

Lorestan province, Khorramabad city, Lorestan university of medical sciences

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Approval date

2017-10-15, 1396/07/23

Ethics committee reference number

IR.LUM.REC.1396.312

Health conditions studied

1

Description of health condition studied

Subclinical Hypothyroidism

ICD-10 code

E02

ICD-10 code description

Subclinical iodine-deficiency hypothyroidism

Primary outcomes

1

Description

Depression

Timepoint

At the beginning of the study and 8 weeks after the intervention

Method of measurement

Depression, Anxiety and Stress Questionnaire with 21 items

2

Description

Anxiety

Timepoint

At the beginning of the study and 8 weeks after the intervention

Method of measurement

Depression, Anxiety and Stress Questionnaire with 21 items

3

Description

stress

Timepoint

At the beginning of the study and 8 weeks after the intervention

Method of measurement

Depression, Anxiety and Stress Questionnaire with 21 items

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The experimental group will participate in an Aerobics exercise program for three sessions (60 min) per week for eight weeks. Both groups will take levothyroxine tablets.

Category

Prevention

2

Description

Control group: Control subjects will not participate in any kind of activity regularly and will only take levothyroxine for 8 weeks.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Lorestan

Full name of responsible person

Vahid Valipour Dehnou

Street address

Km 5 of Tehran road - Khorramabad city - Lorestan province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Lorestan university

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Lorestan university

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Lorestan University

Full name of responsible person

Vahid Valiopour Dehnou

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The only consequence of this is the sharing of data

When the data will become available and for how long

Start the access period after printing the results

To whom data/document is available

Researchers

Under which criteria data/document could be used

-

From where data/document is obtainable

-

What processes are involved for a request to access data/document

-

Comments